K102466

510(k) Summary -

MAY 25 2011

Fujinon EPX-4440 HD Digital Video Processor

Date Prepared: May 25, 2011

Sponsor:

Fujinon, Inc.
10 High Point Drive
Wayne, NJ 07474

Contact:

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Trade name: Fujinon EPX-4440HD Video Processor and Light Source

Common name: Endoscopic Video Processor and Light Source

Classification name:

- Endoscopic Video Imaging System/Component, Gastroenterology-Urology (Product Code FET) and Light Source, Endoscope, Xenon Arc (Product Code GCT)
- Both product codes are covered under 21 CFR 876.1500
- Predicate device(s): Fujinon 400 Series (K944620)

Device description:
This system is intended to be used in conjunction with Fujinon endoscopes to provide illumination, visual display and data storage during endoscopic procedures.

The EPX-4440HD Digital Video Processor consists of three components used in conjunction with one another:

The VP-4440HD Video Processor: The Processor relays the image from the endoscope to a video monitor. Projection can be either analog or digital at the user's

preference. The Processor also incorporates internal or external digital storage capacity. The Processor also controls the light projected to the body cavity. The Processor also provides for optional structural enhancement at the user's option. Spectral and structural enhancements are achieved through proprietary software. The device is AC operated at a power setting of 120V/60MzJO.8A. The Processor is housed in a steel-polycarbonate case measuring 390XI05X460mm.

The XL-4450 Light Source: The Fujinon endoscope employs fiber bundles to transmit light from the light source and subsequently to the body cavity. The Light Source employs a 300W Xenon lamp with a 75W emergency back-up Halogen lamp. Brightness control is performed by the user. The device is AC operated at a power setting of 120V/*60MzJ3.3A*. The Processor is housed in a steel-polycarbonate case measuring 390X155X485mm.

The DK-4440E Keyboard: The Keyboard is used to enter pertinent procedural information (patient, physician, date, etc) for display on the video monitor and digital/analog storage systems. The Keyboard is also used to control operational features of the VP-4440HD Processor. The Keyboard resembles a standard computer keyboard in size and shape.

Intended Use(s):

The VP-4440HD unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using Fujinon medical Endoscope, light source, monitor, recorder and various peripherals.

The XL-4450 light source is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to provide illumination to an endoscope. The light source also functions as a pump to supply air through the endoscope while inside the body to assist in obtaining clear visualization to facilitate diagnostic examination. This product may be used on all patients requiring endoscopic examination and when using Fujinon medical Endoscope, digital video processor, monitor, recorder and various peripherals.

Technological characteristics: The subject device is a modification of the current Fujinon Video Processor. Basic technological characteristics have not changed. The Video Processor, Light Source and Keyboard remain essentially unchanged from the predicate device with the exception of additional cabling connections. The processor has been updated to allow for both digital and analog outputs. Previously these outputs were analog only with no digital storage capacity. Digital storage capability can be achieved by on-site storage (internal or CF card) or off-site (Ethernet).

The Processor now incorporates a new connector for the 500 series of Fujinon endoscopes as well as the original series 400 scopes. The above changes were made for the purposes of user preference and general technological advancement; they were not the result of product recalls or adverse events.

Non-clinical testing:

The EPX-4440HD Digital Video Processor is non-sterile and has no potential for patient contact. Testing of the VP-4440HD consisted of software validation electrical safety in accordance with IEC 60601 requirements and performance testing using physician evaluators. All testing criteria were met.

Non-clinical testing of the subject device consisted of electrical testing in accordance with IEC 60601 requirements, software validation in accordance with IEC 62304 requirements and physician evaluation of the spectral enhancement capability. Functional testing consisting of visual comparison tests were conducted using physician evaluators. In all cases they passed the required testing regimens. The sponsor believes that the testing regimen demonstrates the continued safety of the subject device.

Clinical testing:

NA

Conclusions:

Modifications to the predicate device consisted of:

Software additions: Allowing for either digital or analog outputs
Addition of optional digital memory storage
Adding an additional port for acceptance of newer generation endoscopes

Changes to the endoscopes were made for purposes of ergonomics and user, preferences. The changes were not made for reasons of product safety or adverse events.

Testing was performed to demonstrate the continued electrical safety of the device and the reliability of the software. The sponsor believes that the modified device maintains the same safety and performance levels as the previous generation processor while adding additional features for user convenience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Fujinon, Inc.
c/o Robert Schiff, Ph.D., RAC, CQA, FRAPS
Regulatory Affairs Consultant
Schiff & Company, Inc.
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

MAY 25 2011

Re: K102466
Trade/Device Name: Fujinon EPX-4440HD Digital Processor and Light Source
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET and GCT
Dated: May 19, 2011
Received: May 20, 2011

Dear Dr. Schiff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (If known): K102466

Device Name: EPX-4440HD Digital Video Processor and Light Source

Indications for Use (VP-4440HD):

The VP-4440HD unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using Fujinon medical Endoscope, light source, monitor, recorder and various peripheral devices.

Indications for Use (XL-4450):

The XL-4450 light source is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to provide illumination to an endoscope. The light source also functions as a pump to supply air through the endoscope while inside the body to assist in obtaining clear visualization to facilitate diagnostic examination. This product may be used on all patients requiring endoscopic examination and when using Fujinon medical Endoscope, video processor, monitor, recorder and various peripheral devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102466